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09/240,675	02/02/1999	PATRICK BENOIT	017283/0123	7649

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

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20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/240,675	Applicant(s) Benoit et al.
Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 7, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 23-26 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23-26 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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DETAILED ACTION

After-Final Amendment

- 1) Acknowledgment is made of Applicants' After-Final amendment filed 12/07/01 (paper no. 19) in response to the Final rejection mailed 08/07/01 (paper no. 17).

Status of Claims

- 2) Claims 23-26 are amended via Applicants' After-Final amendment filed 12/07/01.

Claims 23-26 are pending and under examination.

Finality Withdrawn

- 3) The finality of the Office Action mailed 08/07/01 (paper no. 17) is hereby withdrawn. Applicants are asked to note the new grounds of rejections made below.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

- 6) The objection to the drawing(s) made in paragraph 7 of the Office Action mailed 09/03/99 (paper no. 7) is maintained for reasons set forth therein. Applicants have resubmitted Figures 2 and 3, which have been approved by the Draftsperson. It is noted that Applicants have not submitted a formal drawing for Figure 1. However, Figure 1, as originally submitted, still remains objected to by the Draftsperson as was indicated in the PTO Form 948 (paper no. 7).

- 7) The objection to the oath or declaration made in paragraph 11 of the Office Action mailed 01/31/01 (paper no. 14) as being defective is maintained for reasons set forth therein and herebelow.

Applicants submit a Declaration by the attorney of record to state that a diligent effort was made to contact all of the inventors, but it was not possible to have the substitute Declaration

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signed by each inventor.

Applicants are reminded that the non-initialed alterations in the oath/declaration are improper. The inability to reach one or more inventors is an issue under 37 CFR 1.47 properly treated by the Office of Petitions. If the attorney is unable to get some of the inventors to reexecute an oath or declaration, the attorney still needs to submit an oath or declaration signed by inventors who are available to reexecute. The attorney also needs to submit a petition under 37 CFR 1.183 to waive the reexecution of an oath or declaration by the inventors who are not reachable to sign. Petitions under 37 CFR 1.183 are decided by the Office of Petitions and should be submitted with proof of unavailability similar to a petition under 37 CFR 1.47.

8) The objection to the specification made in paragraphs 13(a), 13(b), 13(c) and 13(d) of the Office Action mailed 01/31/01 (paper no. 14) is maintained for reasons set forth therein. The specification continues to refer to SEQ ID NO: 1 as an amino acid sequence (see pages 8, 10 and 14, for example), whereas the Sequence Listing and/or the Figure refer to SEQ ID NO: 1 as a nucleotide sequence.

Objection(s) Withdrawn

9) The objection to the title made in paragraph 12 of the Office Action mailed 01/31/01 (paper no. 14) as being non-descriptive is withdrawn in light of Applicants' amendment to the title.

10) The objections to the specification made in paragraphs 13(b), 13(c) and 13(d) of the Office Action mailed 01/31/01 (paper no. 14) are withdrawn in light of Applicants' amendments to the specification.

11) The objection to claim 25 made in paragraph 18 of the Office Action mailed 01/31/01 (paper no. 14) is withdrawn in light of Applicants' amendments to the claim.

Rejection(s) Withdrawn

12) The rejection of claims 23-26 made in paragraph 14(a) and 14(b) of the Office Action mailed 01/31/01 (paper no. 14) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

13) The rejection of claims 23-26 made in paragraph 16 of the Office Action mailed 01/31/01

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(paper no. 14) under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendments to the claims. It is noted that Applicants have amended the claims to delete the reference to the peptide as SEQ ID NO: 1, which is a nucleotide sequence as opposed to an amino sequence.

14) The rejection of claims 23-25 made in paragraphs 17 and 19 of the Office Action mailed 09/08/00 and 01/31/01 respectively (paper no. 10 and 14) under 35 U.S.C § 102(a) and maintained in paragraph 13 of the Office Action mailed 01/31/01 (paper no. 14) as being anticipated by Racaniello *et al.* (WO 9203538 - already of record), is withdrawn.

Rejection(s) Maintained

15) The rejection of claim 24 made in paragraph 15 of the Office Action mailed 01/31/01 (paper no. 14) under 35 U.S.C. § 112, first paragraph, as containing new matter, is maintained for reasons set forth therein and herebelow.

Applicants cite case law and contend that it is not necessary that the application describe the claim limitations exactly. Applicants assert that the claimed invention does not have to be described in *ipsis verbis* in order to satisfy the description requirement under 35 U.S.C. § 112, first paragraph. Applicants state that the written description requirement is satisfied when each claim limitation is supported explicitly, implicitly or inherently "in the originally filed disclosure". Applicants point to lines 22-27 on page 8 of the specification and state that a peptide consisting of amino acids 1 to 229 of SEQ ID NO: 2 described in Figure 2 is described. Applicants state that this part of the specification discloses that a peptide consisting of amino acids 1 to 229 of SEQ ID NO: 2 is advantageous for preparing antibodies which specifically recognize human IFN-R. Applicants contend that the original claims 9 and 12 and the specification at page 10, lines 11-16, disclose an antibody specific for an epitope on the peptide consisting of amino acids 27 to 427. Applicants further contend the following:

Applicants assert that an artisan reading the disclosure would recognize readily that Applicants had determined, by the time the application was filed, that amino acids 1 to 26 and 230 to 427 of SEQ ID NO: 2 were not essential for the proper folding of the extracellular domain of the IFN-R encoded by amino acids 27 to 427. Thus, one of ordinary skill in the art would recognize that Applicants had possession of a peptide consisting of an amino acid sequence from position 27 to position 229 of SEQ ID NO: 2, wherein the peptide or portion thereof specifically binds to monoclonal antibody 64G12.

Applicants' arguments have been carefully considered, but are non-persuasive. Claim 24 is directed to an isolated peptide or polypeptide "consisting of" an amino acid sequence from position "27 to 229 of SEQ ID NO: 2 or a portion thereof. The claimed peptide is required to bind specifically to the specific monoclonal antibody, 64G12. Figure 2 depicts a peptide of SEQ ID NO: 2 consisting of about 436 amino acids. Lines 22-27 on page 8 disclose that an advantageous peptide corresponds to the amino acid sequence comprised between amino acid 1 and 229. The original claims 9 and 12 and the specification at page 10, lines 11-16 describe an antibody directed to a genus peptide comprised between amino acid residue 27 and 427. These parts of the specification neither describe a subgenus peptide "consisting of" an amino acid sequence from position 27 to position 229 of SEQ ID N: 2", or "a portion thereof", nor the functional limitation that such a specific subgenus peptide or its portion specifically binds to the monoclonal antibody, 64G12. There was no conception or contemplation in the specification, as originally filed, that of a subgenus peptide or polypeptide "consisting of" an amino acid sequence from position 27 to 229 of SEQ ID NO: 2, or a portion thereof. Furthermore, the specification, as originally filed, is devoid of a teaching of the specific binding function of any monoclonal antibody, or 64G12 monoclonal antibody in particular, with a peptide or polypeptide "consisting of" amino acid residues 27-229 of SEQ ID NO: 2, or a portion thereof. The subgenus 27-229 peptide of SEQ ID NO: 2 does not have corresponding written description so specific as to lead one having ordinary skill in the art to that class of peptide compound and its specific binding to any monoclonal antibody of the instant invention, including the specific 64G12 monoclonal antibody. New matter includes not only the addition of wholly unsupported subject matter, but also include adding specific compounds, i.e., peptides in this case, after a broader original disclosure. From the specification which discloses a peptide or polypeptide consisting of amino acid residues 27-427 of SEQ ID NO: 2 that binds with 64G12 monoclonal antibody, one of ordinary skill in the art would not recognize that Applicants had possession of a subgenus peptide or polypeptide consisting of an amino acid sequence from position 27 to position 229 of SEQ ID NO: 2, wherein the peptide or polypeptide or a portion thereof specifically binds to the monoclonal antibody, 64G12. Furthermore, while Table 1 indicates that amino acids 1 to 26 of the polypeptide may not be needed for binding with the 64G12 monoclonal antibody, there is **no**

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disclosure or contemplation in the specification, as originally filed, that amino acids 230 to 427 of SEQ ID NO: 2 were non-essential for the proper folding of the extracellular domain of the IFN-R or for specific binding with the recited monoclonal antibody. Without such a specific disclosure in the specification as originally filed, one of ordinary skill in the art cannot guess or assume what part of a specific protein would or would not be required for proper folding.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

16) Claims 23, 25 and 26 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 23 is directed to an isolated peptide or polypeptide “consisting of an amino acid sequence” from position 27 to position 427 of SEQ ID NO: 2, or a portion thereof having specific binding ability with the 64G12 monoclonal antibody. While there is descriptive support in the instant specification for such a 27-427 peptide that specifically binds to the 64G12 monoclonal antibody (see Table 1), there appears to be no descriptive support for “a portion” of the peptide that specifically binds to the 64G12 monoclonal antibody.

Claim 25 is directed to an isolated peptide or polypeptide “consisting of an amino acid sequence” from position 1 to position 229 of SEQ ID NO: 2, or a portion thereof having specific binding ability with the 64G12 monoclonal antibody. While there is descriptive support in the instant specification for a 1-229 peptide (see page 8, lines 25-27), there appears to be no descriptive support for this subgenus peptide or “a portion” of the peptide that specifically binds to the 64G12 monoclonal antibody (see Table 1).

Claim 26 is directed to an isolated peptide or polypeptide derived from a peptide or polypeptide of claim 23 (i.e., the 27-427 peptide of SEQ ID NO: 2) by substitution of one or more amino acid residues, which retains the ability to specifically bind to the “monoclonal antibody 64G12”. There is general description in the instant specification in the last paragraph of page 8 for antibodies that can be prepared against a generic polypeptide modified by substitution of one or more amino acids provided that antibodies directed against the nonmodified extracellular domain of the IFN-R recognize the modified polypeptide or peptide. However, no

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descriptive support exists for a specific variant of the 27-427 peptide of SEQ ID NO: 2 which specifically binds to the specific monoclonal antibody, 64G12.

Therefore, the claimed peptides or polypeptides are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claims, or point to the specific parts of the disclosure, as originally filed, that provide descriptive support for the limitations.

Rejection(s) under 35 U.S.C. § 102

17) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

18) Claim 23 is rejected under 35 U.S.C § 102(e) as being anticipated by Urban *et al.* (US 5,880,103).

Due to the lack of descriptive support in the instant application for the recitation “a portion thereof” of a peptide or polypeptide consisting of 27 to 427 and having the specific binding ability to the 64G12 monoclonal antibody, instant claim is afforded the filing date of 02/02/99.

Urban *et al.* disclose a peptide or polypeptide consisting of “a portion” of a peptide or polypeptide consisting of an amino acid residues from position 27 to position 427 of SEQ ID NO: 2. See the line that recites IFN-alpha receptor in Table 8: GNHLYWKWKQIPDCENVK. This 17-mer peptide has 100% sequence identity with a “portion” of the peptide or polypeptide claimed in claim 23. Although Urban *et al.* is silent about the specific binding of the prior art IFN-alpha receptor to the specific monoclonal antibody recited in the instant claim, the prior art peptide is viewed as the same as the Applicants’ “portion” of the peptide or polypeptide of claim

23. Since the prior art peptide is structurally same as the "portion" of the peptide or polypeptide of claim 23 and is long enough to serve as an antigenic epitope, it is expected to bind to Applicants' specific monoclonal antibody, 64G12, which was inaccessible to Urban *et al.* at that time. The property of binding to the specific monoclonal antibody recited by the Applicants is inherent to the 17-mer peptide of Urban *et al.* That a 17 amino acid residue-long peptide constitutes an antigenic determinant or epitope is inherent from the teaching of Urban *et al.* in light of what is well known in the art that a peptide having as little as six amino acid residues bind to specific antibodies.

Claim 23 is anticipated by Urban *et al.*

- 19) Claim 23 is rejected under 35 U.S.C § 102(b) as being anticipated by Benoit *et al.* (*J. Immunol.* 150: 707-716, 01 February 1993 - Applicants' IDS).

Due to the lack of descriptive support in the instant application for the recitation "a portion thereof" of a peptide or polypeptide consisting of 27 to 427 and having the specific binding ability to the 64G12 monoclonal antibody, instant claim is afforded the filing date of 02/02/99.

Benoit *et al.* teach an isolated polypeptide consisting of an amino acid sequence consisting of residues from 27 to 427 of the human IFN-alphaR. The polypeptide binds specifically to the monoclonal antibody (see left column on page 709; and right column on page 711). Although the prior art does not expressly disclose that the polypeptide is of the amino acid sequence of SEQ ID NO: 2, the instantly recited SEQ ID NO: 2 is viewed as being the inherent sequence identifier used to identify the prior art polypeptide.

Claim 23 is anticipated by Benoit *et al.*

Remarks

- 20) Claims 23-26 stand rejected.
- 21) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone

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number is (703) 308-4242, which receives papers 24 hours a day, seven days a week.

22) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



S. DEVI, PH.D.
PRIMARY EXAMINER

January 2002